K062780

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS for ClickZip Needle Retractable Safety Syringe Insulin 1 ml. (per 21CFR807.92)

1. SUBMITTER's NAME

JAN - 5 2007

Medical Device Manufacturer (Thailand) Ltd.
7/145 Amata City Industrial Estate
Pluakdaeng, Rayong 21140
Thailand

Contact: Ms. Oytip Kunwunlop, Compliance Director
Phone: 66 1 844 7959
Fax: 66 38 956 429

2. DEVICE NAME

Trade Name: ClickZip™ Needle Retractable Safety Syringe Insulin 1 ml.
Common Name: Safety Syringe
Classification: II
Classification Name: Piston Syringe with Safety Feature
Classification Code: MEG
Nominal Capacity: 1ml.
Insulin Unit: U-100

3. PREDICATE DEVICE

- 1cc Insulin SafePro Safety Syringe with 510(K) number K050134
- ClickZip™ Needle Retractable Safety Syringe with 510(K) number K051694

4. DEVICE DESCRIPTION

The ClickZip™ Needle Retractable Safety Syringe Insulin 1 ml. is sterile, single-use, disposable and non-reusable, needle retractable safety syringe, provided with various size of needle.

5. INTENDED USE

The ClickZip™ Needle Retractable Safety Syringe Insulin 1 ml. with U-100 strength insulin is to be used for subcutaneous injection of insulin into a patient and is intended to prevent needle stick injuries.

In addition, when the syringe user breaks the plunger, re-use of the syringe is prevented.

6. COMPARISON of MODIFIED & PREDICATE DEVICE and SUBSTANTIAL EQUIVALENCE

Medical Device Manufacturer (Thailand) Ltd. makes a claim of substantial equivalence of the ClickZip™ Needle Retractable Safety Syringe Insulin 1 ml. to the cited predicates based on similarities in intended use, design, technological and operational characteristics. The syringes are indicated for injecting insulin into the body, while helping to prevent needle stick injuries. ClickZip™ is supplied with needle attached while SafePro is supplied with or without needle packing.

All syringes requires the user to manually activate the safety mechanism. This is done by retracting the needle into the syringe barrel, breaking off the plunger and discarding the pieces.

Medical Device Manufacturer (Thailand) Ltd. believes that the difference between the ClickZip™ Needle Retractable Safety Syringe and the predicate device are minor and they raise no new issues of safety or effectiveness.

7. PERFORMANCE SUMMARY

ClickZip™ Needle Retractable Safety Syringe Insulin 1 ml. has been shown to meet internationally recognized standards for syringe performance i.e. ISO 7864, ISO 8537, ISO 10993 series, and ISO 11135. These include physical specification, chemical specification, biocompatibility and sterilization specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2007

Ms. Oytip Kunwunlop
Compliance Director
Medical Device Manufacturer (Thailand) Limited
7/145 Moo 4
Amata City Industrial Estate
Rayong, Thailand 21140

Re: K062780
Trade/Device Name: ClickZip™ Needle Retractable Safety Syringe Insulin 1 ml.
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: November 23, 2006
Received: November 29, 2006

Dear Ms. Kunwunlop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

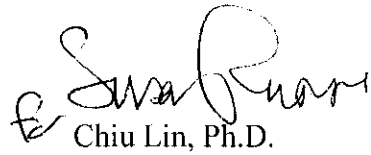
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510K Number (if known): K062780

Device Name: ClickZip™ Needle Retractable Safety Syringe Insulin 1 ml.

Indications for Use:

The ClickZip™ Needle Retractable Safety Syringe Insulin 1 ml. with U-100 strength insulin is to be used for subcutaneous injection of insulin into a patient and is intended to prevent needle stick injuries.

In addition, when the syringe user breaks the plunger, re-use of the syringe is prevented.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter ✓
Use_____
Per 21 CFR 801.109

(Optional Format 1-2-96)

[illegible] General Hospital
[illegible] Medical Devices

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